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Subject: Environmental Defense comments on N-n butylbenzenesulphonamide (CAS# 3622-84-2)

(Submitted via Internet 6/25/04 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, lucierg@msn.com and Wendy.Hulsbosch@Taminco.com)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for N-n butylbenzenesulphonamide (CAS# 3622-84-2).

The test plan and robust summaries for N-n-butylbenzenesulphonamide (BBSA) were submitted by Proviron Fine Chemicals. BBSA is used as a plasticizer in polyacetals, polycarbonates, polysulphones and Nylon 11 and 12. According to the test plan no occupational safety standard has been established and no information is provided on exposure levels in the workplace. Likewise, no information is provided on the levels of BBSA in the general environment, in waste streams and in people exposed to this chemical. The CDC has reported on body burdens of several plasticizers during the last two years. Has BBSA been included in those reports? This issue is an important one, since BBSA seems relatively resistant to biodegradation and the CDC has reported that human body burdens of potentially toxic metabolites of several plasticizers are considerably higher than would have been expected based on uses identified by manufacturers and marketers of these substances. Are any data available on the metabolism of BBSA in mammals?

The sponsor has identified some data gaps for the SIDS endpoints and studies are proposed to address those gaps. Specifically, a combined reproductive/ developmental toxicity study is proposed, along with a chromosomal aberration study. We concur that the proposed studies are needed to meet the requirements of the HPV program and that the oral route of administration should be used for the combined study. However, we have several questions and comments regarding the information presented in the test plan and robust summaries. These are as follows:

1. The repeat dose study appears to be of high quality, and it indicates that BBSA has multiple toxic properties. It can produce adverse effects in the liver, kidney, and immune system, and can cause a degeneration of nerve fibers in the spinal cord and sciatic nerve. Are there neurobehavioral manifestations of the reported nerve damage?

2. Experimental data are available for aquatic invertebrates and algae. Fish toxicity data were obtained from an ECOSAR model. While we support use of this model, we question the rankings and description of the studies in the test plan. The sponsor states that fish are intermediate in sensitivity between algae and aquatic invertebrates. The experimental and modeling data seem to indicate that all three aquatic toxicology endpoints should be classified as moderately toxic, with no distinctions made between the endpoints. In general, it appears that the models under-predict the aquatic

toxicity of BBSA.

3. The robust summaries present LC50 values for toxicity to aquatic invertebrates and algae, yet the doses used to obtain these values are not presented. Likewise, the experimental doses are not provided for the acute toxicity studies. The revised plan needs to indicate the doses used because without this information the adequacy of the studies cannot be judged.

4. The acute toxicity LD50 in rats is reported as 2070 mg/kg. However, in the repeat dose study most of the rats were dead or moribund after receiving 1000 mg/kg/day. This finding indicates that BBSA accumulates in mammalian bodies and/or it causes progressive and cumulative damage. Are data available that address either of these possibilities? If so, they should be presented in the revised submission.

Thank you for this opportunity to comment.

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